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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,272	04/19/2000	Li Fang	913.6600CIP	3198

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IP DEPARTMENT OF PIPER RUDNICK LLP
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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

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DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/552,272

Applicant(s)

FANG ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 1, 3, 6-9, 11-13, and 16-57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 11-19-02.

Applicant's arguments filed 3-24-03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the claims as amended, along with the detailed specification, offer ample support to show that the Applicants were in possession of the claimed invention at the time the application was filed. Applicants, argue that the Federal Circuit has consistently held that the requirements of § 112 are met despite the need for some experimentation by those skilled in the art. Moreover, Applicants reference U.S.S. v. Tele Electronics, Inc., wherein the court held that "the test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent, coupled with the information known in the art, without undue experimentation." However, contrary to Applicant's assertions, the instant rejection is not based upon one of lack of enablement, on the contrary the instant rejection is based upon the specification's lack of an adequate written description of the isolated nucleic acid sequences claimed by Applicants. Although the specification as filed may be enabled for making and using the claimed invention,

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nonetheless the specification may not adequately describe the claimed invention. The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement).

Claim 1 has been amended to recite “wherein said isolated nucleic acid molecule is mediated by a portion of a 5’-UTR of the cold shock inducible gene or a substantially homologous sequence thereof.” First it is noted that Applicants do not provide any express support for this amendment. Although originally filed claim 2 provide support for wherein the isolated nucleic acid comprises “a 5’-UTR of the cold shock inducible gene or a substantially homologous sequence thereof,” there is no support for wherein the isolated nucleic acid molecule is *mediated* by a portion of “a 5’-UTR of the cold shock inducible gene or a substantially homologous sequence thereof.”

Moreover, Applicants have added claim 57, however Applicants make no mention as where support can be found for adding the new limitations found in this claim in either the specification as filed or in the original claims. As per MPEP 714.02 and § 2163.06, “[A]pplicant should show support in the original disclosure for the new or amended claims.” Additionally, “[A]pplicant should * * * specifically point out the support for any amendments made to the disclosure,” see also MPEP § 2163.

The instant claims read on a broad genus of nucleic acid molecules that function to prolong the expression of a cold shock inducible gene, wherein said isolated nucleic acid molecule “is mediated by a portion” a 5’-UTR of a cold shock inducible gene, sequences that are

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substantially homologous to said cold shock inducible genes, including all polymorphic and allelic variants of nucleic acid molecules that are mediated by a portion of a 5'-UTR of a cold shock inducible gene, and sequences isolated from any organism. However, Applicant's describes only the 5'-UTR of the cold shock inducible genes according to the *cspA*, *cspB*, and *csdA* genes. Applicant's description of the nucleic acid molecules according to the *cspA*, *cspB*, and *csdA* genes, is not commensurate in scope with the broad genus of nucleic acid molecules encompassed by the instant claims, such that the ordinary skilled artisan can use the description set forth in the specification as filed to predict the structures of all members of the broad genus of molecules encompassed by the instant claims. It is evident that further experimentation would be required in order to identify those sequences that are substantially homologous to the sequences of (for example) the *cspA*, *cspB*, and *csdA* genes, and furthermore to identify those substantially homologous sequences that function to prolong the expression of a cold shock inducible gene, or wherein said sequence functions to enhance translation of a gene under conditions that elicit a cold shock response in a bacterium. The fact that further experimentation is required indicates that the full scope of the claimed invention was not reduced to practice at the time of filing of the instant application.

Possession cannot be demonstrated by a means for isolating an invention, [A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that

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show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.” See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1.

As stated in the prior Office Action, the full scope of the claimed invention was not “ready for patenting” at the time the invention was filed. Therefore, applicant was not in possession of the full scope of the claimed invention at the time of filing of the instant application.

Response to Arguments

3. Claims 1, 3, and 5-15 remain rejected, and claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. for the reasons of record set forth in the Official Action mailed 9-13-01.

Applicant's arguments filed 2-22-02 have been fully considered but they are not persuasive. Applicants traverse the instant claims on the grounds that Goldstein provides only a preliminary description of the cspA gene, and that nothing in Goldstein et al. indicates the regulation, induction and control of the cspA gene. However, contrary to Applicant's assertions, Goldstein et al. disclose the nucleic acid sequence encoding the entire cspA gene cloned into the pJJG01 vector, and further discloses E. coli bacteria comprises the pJJG01 vector, and the sequence cspA gene sequence comprises promoter elements that are recognized by RNA polymerase present in E. coli bacteria (see page 286, col. 2, paragraph 2, lines 7-8 and Figure 5B). The claims do not require that the prior art teach regulation, induction and control of the cspA gene. The prior art vector and cloned sequence discloses enough information to cause the

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expression of this gene in bacteria cells, although Applicants state that the expression was transient, it was nonetheless expressed to some extent. Moreover, the claims to not require the prolonged expression of the *cspA* gene product in cells.

4. Claims 1, 3, and 5-6 remain rejected, and claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Oppenheim et al. (US Patent No. 5,726,039) or Oppenheim et al. (US Patent No. 5,654,169).

Applicant's arguments filed 2-22-02 have been fully considered but they are not persuasive. Applicants traverse the instant claims on the grounds that the "promoter fragment" used in the constructs of Oppenheim et al. do not comprise a 5'-UTR sequence. However, contrary to Applicant's assertions, it is noted that one of the promoter fragments disclosed by Oppenheim et al. comprise 449 nucleotides before the start codon, see Figure 19. A sequence of 449 nucleotides beyond the start codon undoubtedly comprises 5'-UTR sequence of the *cspA* gene, and furthermore this 5'-UTR sequence was able to drive the temporal cold-shock expression of *lacZ*. Applicant's arguments do not take the place of evidence; the instant claims remain rejected for the reasons of record.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

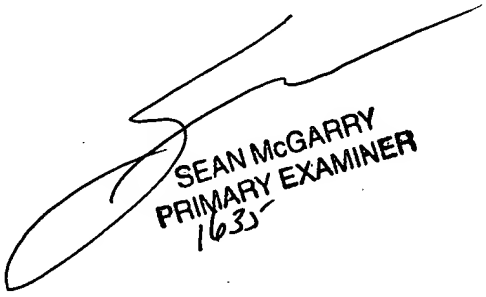
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
June 16, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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